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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,960	02/14/2002	Leonid Metzger	1662/56202	8710

26646 7590 09/24/2003

KENYON & KENYON  
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NEW YORK, NY 10004

EXAMINER
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BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/24/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/073,960

Applicant(s)

METZGER et al.

Examiner

Emily Bernhardt

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/19/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3-10, 12-17, and 20-26 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12-16, and 20-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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**In view of applicants' response filed 6/19/03 the following still applies.**

**Claims 1,3-6,12 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**1. Reason # 1 of the previous action remain for claims 1, 3-6 as well as new 20-22 . It is agreed that a mere difference in scope is enough but none is seen from a reading of the specification. The sole preparative example that makes the dihydrate has all the characteristics recited in claims 3-6 as well as in new claims 20-22. Specification does not make any distinctions as to difference in purity levels. The same compound is being covered regardless what is being measured. Thus, reciting additional properties for the same compound where no distinction as to purity for example is made in the specification renders the difference in scope unclear.**

**2. Claim 12 now dependent on new claim 25 is unclear as to intended scope. In view of the "comprises" language in 12 it is not clear if only the ketone recited is being claimed or mixtures thereof. Clarification is needed.**

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**Claims 7-10, 12-16 and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Main claim 7 no longer recites an organic solvent which is always necessary (not optional) in making the dihydrate. Compare with specification beginning on p.3 which includes the presence of certain organic solvents as an essential step. Thus the process claims lack critical features necessary to practice the invention. Note also that the heating step is mandatory (not optional) as well as the neutralization with acid as also seen from a reading of the specification . Note MPEP 2164.08(c).**

**Claim 17 is allowed.**

**THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

**A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action**

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and the advisory action is not mailed until after the end of the  
THREE-MONTH shortened statutory period, then the shortened statutory  
period will expire on the date the advisory action is mailed, and any extension  
fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the  
advisory action. In no event, however, will the statutory period for reply  
expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Emily  
Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of  
operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier  
numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-  
3592.



**EMILY BERNHARDT**

**PRIMARY EXAMINER**

**ROUP 1600**